IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re: Testosterone Replacement	**)**	
Therapy Products Liability Litigation	**)**	**Case No. 14 C 1748**
Coordinated Pretrial Proceedings	**)**	**MDL No. 2545**
	)	
This document applies to all cases	**)**	
and to *Nolte v. AbbVie, Inc. et al.*,	**)**	
Case No. 14 C 8135	**)**	

CASE MANAGEMENT ORDER NO. 94
(rulings on motions *in limine* in
***Nolte v. AbbVie, Inc. et al.*, Case No. 14 C 8135)**

MATTHEW F. KENNELLY, District Judge:

Plaintiff Robert Nolte has sued defendants AbbVie, Inc. and Abbott Laboratories (collectively, AbbVie), alleging that AbbVie's testosterone replacement therapy (TRT) drug AndroGel caused him to suffer a pulmonary embolism—a sudden blockage of a blood vessel in the lungs. Nolte asserts that AbbVie misleadingly marketed AndroGel as being safe and effective for the treatment of age-related hypogonadism, that is, low testosterone levels in the blood, and accompanying signs and symptoms, brought about by the normal male aging process. He also asserts that AbbVie failed to adequately warn that AndroGel use could cause venous thromboembolic (VTE) injuries, such as a pulmonary embolism or deep-vein thrombosis.

Nolte's is the fourth "bellwether" case in this multidistrict litigation proceeding to go to trial. The Court issued rulings on motions *in limine* in advance of each of the first three trials, two of which also involved AbbVie as a defendant. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings* (Holtsclaw MIL Ruling), No. 14 C 1748, 2017 WL 5029601 (N.D. Ill. Nov. 3, 2017) (rulings on

motions *in limine* in case brought against defendant Auxilium Pharmaceuticals, Inc.); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings* (Prior AbbVie MIL Rulings), No. 14 C 1748, 2017 WL 2313201 (N.D. Ill. May 29, 2017) (rulings on motions *in limine* in two cases brought against AbbVie). Both sides have asked the Court to adopt its prior rulings in this case, and the Court does so, except as discussed below.

This case also presents certain new issues. Each plaintiff in the prior bellwether cases, for example, alleged that TRT caused him to suffer a cardiovascular injury (heart attack or stroke). Nolte's case thus will be the first one involving an alleged VTE injury to be tried. In light of the alleged injury and other issues specific to Nolte's case, the parties have moved to exclude additional items of evidence that were not addressed in prior rulings. The Court assumes familiarity with those rulings for purposes of this opinion.

A. Evidence Nolte has moved to exclude

1. 2014 Public Citizen letter and response from the FDA

Nolte has moved to exclude evidence of a 2014 letter sent by the advocacy group Public Citizen to the FDA, as well as the FDA's response to that letter. In the letter, Public Citizen asked the FDA to require additional warnings about the increased risk of cardiovascular injuries associated with TRT use. In prior cases, the Court determined that the letter and the FDA's response denying Public Citizen's request were relevant and admissible on the issue of whether TRT causes cardiovascular injuries. Nolte contends that the evidence is irrelevant in this case because Nolte does not allege that he suffered any cardiovascular injury. AbbVie agrees that the Public Citizen letter

and the response from the FDA are irrelevant; it asks the Court to exclude *all* evidence relating to the purported cardiovascular risks associated with TRT use, a request the Court will discuss later in this order. Nolte's motion concerning the Public Citizen letter and the FDA's response is unopposed, and the Court grants the motion.

2. History of alcohol use and alcohol-induced pancreatitis

The remainder of Nolte's motions *in limine* concern aspects of his medical history that AbbVie's expert witnesses might opine to be risk factors for a pulmonary embolism or for hypogonadism. Nolte contends that there is insufficient evidence linking those medical conditions to the pulmonary embolism he suffered or to his hypogonadism diagnosis, and he maintains that any probative value of testimony about those conditions is substantially outweighed by the risk of unfair prejudice to him. AbbVie charges that Nolte's effort to exclude the testimony of AbbVie's experts is effectively a belated *Daubert* challenge. Just as the Court permitted Nolte's expert, Dr. Rinder, to consider multiple sources of evidence to establish causation based upon the "totality of the evidence," AbbVie argues that the Court should allow AbbVie's experts to testify broadly about potential risk factors, including those that have weaker support in the scientific literature or a weaker connection to Nolte's case than other factors.

The Court believes that both parties' comparisons to prior *Daubert* rulings are misplaced. Nolte, for example, faults AbbVie's experts for failing to establish that certain purported risk factors were "substantial contributing factors" in causing his injury. It is true that Nolte has to establish that AndroGel was a substantial contributing factor to his injury to satisfy the causation element of his claims, and thus the admissibility of his experts' testimony on causation depends, in part, on whether the testimony satisfies

that standard. *See Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) (considering state law's "substantial factor" standard for causation in determining admissibility of expert witness' causation testimony). But AbbVie does not carry the same burden to establish conclusively that any one factor caused Nolte's injury, and thus an opinion from one its experts that some factor *may* have contributed to the injury could be relevant and admissible.

At the same time, AbbVie unduly emphasizes the fact that the Court permitted Dr. Rinder and other experts to testify about causation opinions based on a "totality of the evidence" method. It is true that the Court found it permissible for experts in this case to base their causation opinions on sources of evidence, like animal studies and *in vitro* studies, that might be insufficient on their own to establish causation. *See In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1833173, at *14 (N.D. Ill. May 8, 2017) (experts may "rely on such studies as part of a much broader set of evidence"). In permitting the testimony, the Court concluded that a "totality of the evidence" method—including consideration of evidentiary sources with varying degrees of strength and quality—may be a reliable basis for a relevant causation opinion. It is a separate question whether the probative value of certain evidence relied upon by an expert is substantially outweighed by its potential for unfair prejudice. If an expert's discussion of animal studies, for example, carried a significant risk of jury confusion or unfair prejudice to AbbVie in a particular case, the expert's testimony about those studies might be inadmissible even if it otherwise satisfied *Daubert*'s admissibility criteria. *See* Fed. R. Evid. 403 ("The court may exclude [even] relevant evidence if its probative value is substantially outweighed

by a danger of . . . unfair prejudice [or] misleading the jury[.]"). And if a defense expert's testimony about a particular risk factor is not tied to evidence that the plaintiff actually had that risk factor, the testimony likely would be irrelevant or at least would be subject to exclusion under Rule 403.

Nolte contends that testimony about his history of alcohol use presents a danger of unfair prejudice against him that substantially outweighs the testimony's probative value. Medical records indicate that in 2008, Nolte was diagnosed with an acute episode of alcohol-related pancreatitis. Medical records also reflect Nolte's apparent report that he later resumed alcohol use and drank scotch on a daily or almost-daily basis at one or more points in time. The Court has previously remarked on the potential for evidence of alcohol use to prejudice a party unfairly by placing him in a negative light before the jury. *See* Prior AbbVie MIL Rulings, 2017 WL 2313201, at *11.

AbbVie first maintains that Nolte's history of alcohol use is relevant because alcohol abuse is a potential risk factor for a pulmonary embolism. But AbbVie's expert, Dr. Kenneth Bauer, opined only that alcohol use was a potential risk factor for a pulmonary embolism and cited no scientific support for that claim. Thus evidence of Nolte's alcohol use has limited probative value in this context and is substantially outweighed by the risk of unfair prejudice.

AbbVie also maintains that Nolte's history of alcohol use is relevant because it explains why he might have discontinued his anticoagulation medication prior to the pulmonary embolism at issue in this case.[1] Drinking alcohol while taking

[1] Nolte was taking anticoagulation medication to treat an earlier pulmonary embolism that he suffered prior to ever taking AndroGel. The pulmonary embolism at issue in this case, which occurred after he began taking AndroGel, was the second pulmonary embolism he has suffered.

anticoagulation medication can increase one's risk of bleeding, but there is no evidence that Nolte decided to stop taking the medication because he was concerned the interaction with alcohol. Any argument of that kind would be based on rank speculation, and thus the probative value of the evidence is also substantially outweighed by the danger of unfair prejudice in this context as well.

AbbVie also suggests that Nolte's alcohol use, rather than his pulmonary embolism, might be the cause of a subdural hematoma (bleeding in the brain) that he suffered in 2014. But AbbVie presents no evidence to support this assertion; it is speculative. Therefore the history of alcohol use also has limited probative value in this context, which again is far outweighed by the risk of unfair prejudice.

Evidence of Nolte's alcohol use arguably has greater probative value on the issue of the underlying cause of his low testosterone level at the time he was prescribed AndroGel. AbbVie's expert, Dr. Mohit Khera, states that a history of alcohol abuse is associated with classical hypogonadism, that is, hypogonadism caused by a specific medical condition rather than the normal male aging process. AbbVie contends that Nolte's blood testosterone level dropped because of alcohol abuse. It cites the aforementioned episode of acute, alcohol-related pancreatitis, before which Nolte's testosterone level was in a normal range, and a testosterone measurement several years later that showed a significantly lower, below-normal level. AbbVie also cites, among other things, statements in Nolte's medical records reflecting his report that he resumed the use of alcohol at some point after his pancreatitis episode—including one report that he was drinking a double scotch at dinnertime six times per week. This evidence, it appears, forms the basis for Dr. Khera's statement that "it is not

unreasonable to assume that Mr. Nolte may have had toxic damage from alcohol to his testicles due to his extensive drinking history." Khera Rep., Ex. 10 to Pl.'s Mot., at 4.

The AndroGel warning label states that the drug is indicated to treat hypogonadism resulting from testicular failure due to toxic damage from alcohol. Given Nolte's allegations that AbbVie promoted AndroGel "off label," the underlying cause of Nolte's hypogonadism is potentially a significant issue. That said, Dr. Khera does not actually opine that Nolte's low testosterone level was caused by alcohol abuse. His statement, quoted above, is hedged in several ways: he says only that it is "not unreasonable" to "assume" that Nolte "may" have damaged his testicles by abusing alcohol. *Id.* Neither Dr. Khera nor any other witness ultimately concludes that Nolte had testicular failure resulting from alcohol-induced damage. Indeed, Dr. Khera states in his report that Nolte's medical records "do not identify a specific cause or 'classical' etiology for his hypogonadism," and his conclusion is that Nolte's hypogonadism "was 'non-classical' or idiopathic [that is, without an identifiable cause] and would now be recognized as AOH [adult-onset hypogonadism]." *Id.* Dr. Khera's own conclusion that Nolte likely had non-classical hypogonadism limits the probative value of his statement regarding the potential effects of Nolte's alcohol use. The probative value of evidence concerning Nolte's alcohol use vis-à-vis the indicated uses of AndroGel is further limited by the fact that Nolte's treating physician did not diagnose him with hypogonadism caused by alcohol use and thus does not appear to have understood he was prescribing AndroGel "on label."

All of that said, the Court believes that given the significance of the on-label/off-label issue in this case, Dr. Khera's testimony on this point as set forth in his expert

report is relevant, and its probative value is not *substantially* outweighed by the danger of unfair prejudice posed by admission of evidence regarding Nolte's alcohol use. The Court therefore overrules Nolte's objection to this evidence. But this does not give AbbVie free rein to overstate the significance of this evidence or to characterize it in an unfairly pejorative way. First, Dr. Khera's testimony on the point is and will be constrained by his report and the way he characterizes the evidence there. Second, AbbVie's counsel and witnesses may not characterize Nolte's alcohol use in the pejorative way counsel did in its written submission and at the pretrial conference—one example being statement to the effect that Nolte "poisoned his pancreas."[2] Third, the manner in which AbbVie's counsel argues the point will be limited by the way Dr. Khera has hedged his opinion. Given these limitations, AbbVie's counsel would be well-advised to seek advance guidance from the Court in order to avoid the potential for a mistrial. Finally, as the Court has ruled, AbbVie may not attempt to suggest or elicit testimony regarding a link between Nolte's alcohol use and his pulmonary embolism, his discontinuance of anticoagulant medication, or his subdural hematoma.

3. History of smoking tobacco

Evidence of tobacco use, like evidence of alcohol use, carries a risk of unfair prejudice. AbbVie contends that Nolte's history of smoking tobacco is relevant because

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[2] The specific statement in AbbVie's written submission is the following: "In July 2012, *after* Plaintiff poisoned his pancreas with alcohol, his testosterone level dropped through the floor to 151 . . . ." Defs.' Resp. to Pls.' Mots. In Limine at 9. Aside from the unduly pejorative reference to poisoning, this statement takes inappropriate liberties with the evidence by suggesting that the tests show a direct relationship between the episode of alcohol use by Nolte that induced the acute pancreatitis and a precipitous drop in his testosterone level. Nolte's testosterone level was normal, at 492, in October 2007. His alcohol-induced acute pancreatitis took place in 2008. The next measurement of his testosterone level—the 151 level—took place *nearly four years later*, in July 2012. There were no intervening tests.

it may have played a role in causing his pulmonary embolism. As with alcohol use, however, Dr. Bauer opined only that tobacco use was a potential risk factor for a pulmonary embolism. He also conceded during his deposition that "tobacco is actually somewhat controversial, although oftentimes people regard it as a risk factor[] in VTE." Bauer Dep., Ex. 8 to Pl.'s Mot., at 221:3–6. And he did not address whether it was significant that Nolte quit smoking cigarettes three years prior to the pulmonary embolism at issue in this case. Evidence of Nolte's tobacco use thus has limited probative value that is significantly outweighed by the substantial danger of unfair prejudice to him.

4. Sleep apnea diagnosis

Nolte was diagnosed with obstructive sleep apnea in October 2013, one year after his pulmonary embolism. He contends that evidence of that diagnosis is irrelevant and unfairly prejudicial, though he does not specify the nature of the purported unfair prejudice. AbbVie maintains that the diagnosis is relevant on the issue of causation. Although Nolte was diagnosed one year after he suffered the pulmonary embolism, Dr. Khera stated in his expert report that, in his experience, sleep apnea often goes undiagnosed for long periods of time. He opines, therefore, that sleep apnea may have been a risk factor that caused the hypogonadism for which Nolte began taking AndroGel, and he cites scientific evidence supporting the connection between sleep apnea and hypogonadism. The Court concludes that the sleep apnea diagnosis is relevant. Nolte contends that there is evidence that TRT use can cause sleep apnea and warns that trial time may be wasted addressing the issue of what came first: the sleep apnea or the hypogonadism. As the Court discussed above, the issue of the

underlying cause of Nolte's hypogonadism is a significant one, and it does not appear that presenting evidence on the connection between TRT use and sleep apnea would require a significant amount of time. It is also true, as discussed above with respect to evidence of alcohol use, that Dr. Khera limits the probative value of this evidence by ultimately determining that Nolte's hypogonadism was adult-onset or idiopathic hypogonadism. But because the risk of unfair prejudice or wasted time is minimal, the Court concludes that the probative value of the evidence is significant enough to warrant admission and denies Nolte's motion.

5. Rheumatoid arthritis diagnosis

Nolte also moves to exclude evidence or argument that he had rheumatoid arthritis, an autoimmune disorder that causes inflammation. AbbVie's expert, Dr. Bauer, opines that rheumatoid arthritis is an established risk factor for VTE injuries. During his deposition, Nolte testified that a urologist told him at some point that he had had a flare of rheumatoid arthritis caused by treatment he was receiving for bladder cancer. AbbVie also points to medical records noting that Nolte had been told he had rheumatoid arthritis.

Nolte emphasizes that there are no medical records from any physician who actually diagnosed him with rheumatoid arthritis, and there is no evidence that he underwent testing to verify that he had this condition. Nolte notes that he has been diagnosed with another inflammatory condition, ulcerative colitis, and there is a dispute between the parties about whether that condition was active at the time of his injury. It is possible, Nolte argues, that evidence about rheumatoid arthritis would confuse the jury into believing that inflammation could have caused his pulmonary embolism even if

his ulcerative colitis was not active at the time of the injury.

AbbVie points to medical records in which physicians have entered a diagnostic code for rheumatoid arthritis or some other reference to the disease. These records contain nothing that documents a physician's diagnosis of rheumatoid arthritis; at most they reflect that Nolte reported that he had been told at some unspecified time that he had the condition. AbbVie also notes that Nolte was taking azathioprine, an immunosuppressant medication used to treat rheumatoid arthritis. But as Nolte notes, that drug can also be used to treat ulcerative colitis.

The admissibility of this evidence presents several issues. The first involves hearsay. AbbVie would not be able to elicit from Nolte at trial testimony that a doctor told him he had rheumatoid arthritis; that would be inadmissible hearsay. But the thrust of what AbbVie seeks to do with respect to the medical records is to introduce evidence that Nolte reported a prior diagnosis of rheumatoid arthritis to medical personnel from whom he sought treatment. This presents an issue of two-level hearsay, requiring both levels to be admissible before the statement may be admitted. Fed. R. Evid. 805. The first level is easy; AbbVie may introduce Nolte's out-of-court statements to medical personnel because they are statements by an opposing party. The Court's initial inclination was that the second level—what Nolte said he had been told in the past—was insurmountable. But upon further review of Federal Rule of Evidence 803(4), it expressly provides that a statement that "describes medical history" that is made for and reasonably pertinent to medical diagnosis or treatment is not excluded by the rule against hearsay. Nolte's statements to medical personnel that he had been diagnosed with rheumatoid arthritis meet this standard. Thus Nolte's reports of his apparent earlier

rheumatoid arthritis diagnosis are not inadmissible under the hearsay rule.[3]

The other two issues regarding the rheumatoid arthritis evidence—its relevance and potential for unfair prejudice—are interrelated. The reports regarding this condition contained in Nolte's medical records are equivocal. As indicated, there is no report containing or describing a contemporaneous diagnosis of rheumatoid arthritis and no testimony by a physician to this effect. All that exists are Nolte's reports to medical personnel about what he had been told in the past. But it appears Nolte repeatedly reported this to medical personnel, indicating that it was not misrecorded and that the report has some basis in fact. Because this evidence suggests a potential alternative cause for Nolte's pulmonary embolism, it is relevant. And the Court concludes that the danger of unfair prejudice—perhaps more specifically, jury confusion arising from the relatively thin evidence—does not substantially outweigh the probative value of this evidence and testimony about it by AbbVie's expert. The Court therefore denies Nolte's motion.

6. Antiphospholipid syndrome diagnosis

Nolte moves to exclude evidence of his history of antiphospholipid syndrome (APS). AbbVie's general causation expert, Dr. Sucha Nand, opines that APS is a risk factor for VTE injuries. As Nolte notes, however, none of the reports prepared by AbbVie's experts contains an opinion that APS was a cause of Nolte's injury. Because AbbVie's specific causation experts did not opine in their expert reports that APS caused Nolte's injury, they may not independently offer that opinion at trial. But Nolte's

[3] AbbVie may not argue or otherwise attempt to suggest, however, that the medical records suggest a *then current* diagnosis of rheumatoid arthritis, because there is no foundation for such an inference. It may be appropriate to redact the records in some appropriate way to preclude speculation by the jury in this regard.

expert, Dr. Rinder, does state an opinion about APS in his expert report: he considers APS a risk factor for VTE injuries but concludes that Nolte's laboratory evaluation found no evidence of APS. AbbVie contends that Nolte's conclusion is mistaken, and AbbVie may appropriately cross-examine Dr. Rinder on this point. *See Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 5258858, at *10 (S.D. Ohio Sept. 10, 2015) (allowing defendant to cross-examine plaintiff's expert regarding alternative causes of injury even though none of defendant's experts offered an opinion in their reports that the alternatives were probable causes of injury).

B. Evidence AbbVie has moved to exclude

1. Causation opinions of Nolte's treating physicians

AbbVie moves to exclude deposition testimony by Nolte's treating physicians regarding the cause of Nolte's pulmonary embolism. Evidence of those opinions should be excluded, AbbVie argues, because (a) Nolte failed to disclose their opinions as required by Federal Rule of Civil Procedure 26(a)(2)(C) and (b) the opinions are speculative and not based on a reliable methodology.

Nolte concedes that the causation opinion offered by Nurse Practitioner Eileen Mahler is inadmissible, and the Court grants AbbVie's motion with respect to that opinion. AbbVie also moves to exclude the opinion of Dr. Anthony Stazzone, Nolte's prescribing physician, but it does not appear that Dr. Stazzone intends to offer an opinion about the cause of Nolte's injury. He testified during his deposition that it is not clear to him whether AndroGel was a cause of the injury. The Court does not expect Dr. Stazzone to offer a specific causation opinion at trial.

AbbVie also moves to exclude evidence of Dr. Ali Madani's opinion concerning

the cause of Nolte's injury. Dr. Madani is the hematologist who treated Nolte several weeks after he suffered the pulmonary embolism at issue. By the time Nolte came to see Dr. Madani, he had stopped taking AndroGel. In a medical record created contemporaneously with his treatment of Nolte, Dr. Madani stated that Nolte's pulmonary embolism was "relatively provoked since he started testosterone gel replacement therapy in September 2012." Ex. 6051.272 to Defs.' Mot. During his deposition, Dr. Madani clarified that he used the phrase "relatively provoked" to mean that TRT may have played a role in causing the pulmonary embolism. Counsel for AbbVie proceeded to question Dr. Madani, over the objection of Nolte's counsel, about whether he believed Nolte's AndroGel use caused the pulmonary embolism.

Before taking Dr. Madani's deposition, AbbVie was fully aware of the apparent causation opinion set forth in his records. And AbbVie plainly appreciated the significance of this point, as indicated by its extensive questioning of Dr. Madani about it during the deposition. The transcript of the deposition makes it clear that AbbVie was able to examine Dr. Madani thoroughly about his opinion on this point. Contrary to the contention in AbbVie's motion, the objection by Nolte's counsel at the deposition did not inhibit or limit AbbVie's questioning of Dr. Madani in any way. Under the circumstances, any failure by Nolte to disclose Dr. Madani's opinion was harmless. *See* Fed. R. Civ. P. 37(c) (party barred from using information or witness not properly disclosed under Rule 26(a) "unless the failure was substantially justified *or is harmless*") (emphasis added); c*f.* Prior AbbVie MIL Rulings, 2017 WL 2313201, at *10 (excluding testimony where AbbVie "failed to explain how . . . failure to disclose was harmless or substantially justified"). AbbVie also argues that it would have filed a *Daubert* motion to exclude Dr.

Madani's expert testimony if it had been properly disclosed. But that is exactly what AbbVie has done via its motion *in limine*. Nothing about Nolte's claimed noncompliance with Rule 26(a)(2)(C) deprived AbbVie of a full and fair opportunity to seek exclusion of Dr. Madani's testimony on this point.

The Court therefore turns to the substance of AbbVie's challenge to Dr. Madani's opinion. The Court determines that Dr. Madani has provided a sufficiently reliable basis for his opinion. In making that determination, it is important to note the limited scope of Dr. Madani's opinion. During his treatment of Nolte, Dr. Madani assessed Nolte's various risk factors for a pulmonary embolism, and he identified Nolte's positive risk factors as "incremental risk factors" that each contributed "to a certain extent to increasing [Nolte's] risk." Madani Dep., Ex. A to Defs.' Mot., at 72:12–25. He also assigned weights to certain factors and considered the temporal proximity between the pulmonary embolism and Nolte's initiation of TRT use. Though he testified that since his diagnosis of Nolte more information about TRT has increased his concern about links between TRT and blood clots, the opinion supported by his contemporaneous records is that his "impression at the time" of treating Nolte was that the TRT contributed to the pulmonary embolism. *Id.* at 137:17–23. Dr. Madani has offered a sufficiently reliable basis to support that limited opinion. To be sure, this opinion, as Dr. Madani has expressed it, has relatively low probative value. And were this the only evidence offered by Nolte on the issue of specific causation, the case might not survive a motion for summary judgment. But this is not the case; Nolte's expert witness Dr. Rinder will offer a more definitive specific causation opinion. The Court concludes that the opinion of Nolte's treating physician about his impression of the cause of the injury

after considering Nolte's risk factors is relevant and properly admissible. However, Nolte may not introduce Dr. Madani's testimony about what he *later* learned about the association between TRT use and blood clots; as elicited in the deposition, this testimony lacks adequate foundation. *See id.* at 71:21-72:2.

2. Dr. Madani's statements about Nolte's viewing TRT advertisements

AbbVie seeks to exclude evidence of another statement from Dr. Madani in Nolte's medical records. In recording the history of Nolte's present illness, Dr. Madani noted that Nolte "started taking testosterone gel replacement based on TV commercials that he had seen for fatigue syndrome." Ex. 6051.270 to Defs.' Mot. AbbVie argues that the statement constitutes inadmissible hearsay and is otherwise irrelevant because Nolte has testified that his decision to take AndroGel was not influenced by any advertisement he saw. Despite his deposition testimony, however, Nolte contends that AbbVie's misleading marketing caused him to take AndroGel. And thus even if Nolte's decision to take AndroGel once it was prescribed for him was not influenced by advertising, it is still possible that his decision to seek TRT treatment in the first place was influenced by advertising he saw. Dr. Madani's statement is plainly relevant, therefore, on the issue of whether the TRT advertisements played a causal role in his use of AndroGel.

Nolte also maintains that the statement is admissible under an exception to the rule against hearsay. *See* Fed. R. Evid. 803(4) (out-of-court statement admissible if statement "(A) is made for—and is reasonably pertinent to—medical diagnosis or treatment; and (B) describes medical history; past or present symptoms or sensations; their inception; or their general cause"). Dr. Madani's statement is admissible, Nolte

argues, because it describes an aspect of his medical history and was made for—and was reasonably pertinent to—Dr. Madani's treatment of him. Nolte contends that it was important for Dr. Madani to know why Nolte was taking TRT so that he could determine whether it was possible to treat Nolte's pulmonary embolism while also treating, or at least not exacerbating, the condition for which Nolte was taking AndroGel. AbbVie responds that the reasons why Nolte was taking TRT were not reasonably pertinent to Dr. Madani's treatment of him because he had already stopped taking AndroGel by the time he saw Dr. Madani. Though Dr. Madani, during his deposition, could not ascribe any particular clinical relevance to his statements concerning television commercials, the fact that he made note of this point in his written record is sufficiently indicates that he considered the information pertinent to his treatment of Nolte. The Court concludes that the statement was reasonably pertinent to Dr. Madani's treatment and is therefore admissible under Rule 803(4).

3. Evidence related to TRT's purported cardiovascular risks

AbbVie argues that evidence concerning TRT's purported cardiovascular risk is irrelevant in a case involving an alleged VTE injury, and it moves to exclude all such evidence. Nolte agrees that evidence concerning cardiovascular risk is inadmissible, but he contends that it would be unfairly prejudicial to exclude all documents relating to cardiovascular risk. He explains that many of those documents also contain relevant and highly probative evidence about, for example, the efficacy of TRT for the treatment of age-related hypogonadism. Though TRT's purported cardiovascular risks are not directly at issue in this case, it would be inappropriate to exclude otherwise admissible evidence simply because it references cardiovascular issues. The appropriate remedy

is redaction of irrelevant material. At the final pretrial conference, the Court directed the parties to confer and attempt to redact irrelevant information regarding cardiovascular risk. If the parties are unable, after good faith efforts, to agree on the appropriate redactions for specific items of evidence, they may present those items to the Court for review and determination.

4. Evidence regarding the 2015 AndroGel labeling change

AbbVie moves to exclude evidence of the change it made to the AndroGel label at the request of the FDA in 2015. AbbVie argues that the portion of the label change concerning cardiovascular risk is irrelevant. The Court agrees that that part of the label change is irrelevant, and Nolte states that he does not intend to introduce that portion of the label. The 2015 label also included new language about the safety and efficacy of AndroGel for treatment of age-related hypogonadism. AbbVie contends that this portion of the label change is also irrelevant because the prior AndroGel label already contained a warning about efficacy for patients, like Nolte, who were over 65. But that warning said only that it had not been determined whether efficacy in those over 65 differed from efficacy for younger patients. The new label went further, saying that safety and efficacy had not been established *at all* in men with age-related hypogonadism, regardless of age. That change is thus relevant and admissible. AbbVie also contends that the 2015 label change is irrelevant in its entirety because it post-dates Nolte's AndroGel use and injury. The Court has already explained that a later label change, and the response of physicians to that change, can be relevant on the question of what a prescribing physician would have done if the drug's label had been different. *See* Prior AbbVie MIL Rulings, 2017 WL 2313201, at *2. The Court

therefore denies AbbVie's motion except with respect to the portion of the label concerning cardiovascular risk.

5. Marketing and promotional materials not seen or relied upon by Nolte or his prescribing physician

In prior cases, the Court has ruled that marketing and promotional materials that were not viewed or relied upon by a plaintiff or his prescribing physician may still be relevant and admissible on the question of the motive and intent underlying a manufacturer's promotional activities. The Court has also noted, however, that when there is little or no evidence linking the plaintiff or his physician to particular materials, the probative value of all promotional materials is more limited. In such cases, only a limited amount of such evidence may be admissible before the danger for unfair prejudice begins to substantially outweigh the probative value. As the Court discussed at the final pretrial conference, exactly where the line is drawn will be determined at trial.

6. Evidence of sales representative meetings with doctors other than Nolte's prescribing physician

The Court's ruling and reasoning with respect to promotional activities generally also applies with respect to meetings of sales representatives. There is evidence that sales representatives communicated with Dr. Stazzone, and Nolte may introduce limited evidence of how it communicated with physicians in order to establish AbbVie's intent or motive with respect to its sales representative campaign.

7. HIM study

AbbVie moves to exclude evidence regarding the so-called "Hypogonadism in Males" (HIM) study. AbbVie funded the study, which produced an estimate that over 13 million men over age 45 may have hypogonadism. Nolte says he intends to offer

evidence of the HIM study to show that AbbVie intended to inflate the market for TRT and promote the drug "off label" for the treatment of age-related hypogonadism. AbbVie contends that evidence of the study is inflammatory and unfairly prejudicial. But the evidence is only prejudicial to AbbVie to the extent that the jury believes that the purpose of the study was as Nolte contends—that AbbVie intended to expand TRT's "off label" market. It is not apparent to the Court how evidence of a study that AbbVie funded would be *unfairly* prejudicial. To the extent AbbVie believes that Nolte will mislead the jury about the purpose and results of the HIM study, AbbVie may rebut Nolte's contentions with its own evidence. The Court denies AbbVie's motion.

8. AndroGel sales figures

AbbVie moves to exclude evidence of AndroGel sales figures, which Nolte offers as evidence of motive. AbbVie cites a prior bellwether case involving defendant Auxilium in which the Court excluded evidence of sales figures for Auxilium's TRT drug. In that case, however, the Court allowed the plaintiff to introduce evidence of Auxilium's profits, in lieu of sales figures, as an indicator of the company's motive. Because Auxilium effectively only sold the TRT product at issue in that case, evidence of its profits was sufficient to permit the plaintiff to make its point regarding motive. If AndroGel-specific data regarding profits were similarly available, the Court would seriously consider excluding AndroGel sales figures while allowing introduction of the profit data (at least if it was produced during discovery). But absent evidence of that sort, the Court concludes that the probative value of sales revenue evidence pertaining to AbbVie's motive is not outweighed by the danger of unfair prejudice. The Court therefore denies AbbVie's motion.

9. Funding decisions related to the "T-Trials"

AbbVie moves to exclude evidence concerning its funding of a coordinated study, referred to as the "T-Trials," that examined the benefit of TRT for men aged 65 and older. AbbVie provided $15 million for the study instead of the requested $25 million. In previous trials, plaintiffs have suggested that the T-trials would have assessed TRT's benefits for all users over age 45 but that AbbVie's decision to provide less funding than requested resulted in a study of only older men. AbbVie contends that the evidence is irrelevant in this case because Nolte is over 65, and thus the T-Trials studied TRT's efficacy for men like him. It also argues that it would be unfair to allow the jury to hear evidence about AbbVie's funding decision with respect to one study without also allowing evidence about other funds AbbVie spent on research and development generally. Nolte responds, in conclusory fashion, that AbbVie's funding decision is relevant for all AndroGel users and is relevant on the issue of AbbVie's failure to establish that AndroGel is safe and effective. Nolte, however, does not address AbbVie's contention that its funding decision is not relevant in this case because Nolte is over 65. It does not appear that the funding decision has significant probative value, even if it is relevant, and the Court concludes that the danger of unfair prejudice warrants exclusion of the evidence in this case.

10. References to meetings between the FDA and AbbVie representatives

AbbVie seeks to exclude all references to certain meetings between the FDA and AbbVie lobbyist Frank Sasinowski. Throughout this litigation, AbbVie has asserted attorney-client privilege to protected details of those meetings contained in an email from AbbVie's outside counsel. AbbVie complains that plaintiffs in prior trials insinuated

that Sasinowksi's meeting with the FDA was part of a secret, improper lobbying effort. In 2005, the FDA indicated that it might propose a guidance for changing the required label for the entire class of TRT drugs. AbbVie responded by submitting formal filing expressing its position on the need for such a label change. According to AbbVie, plaintiffs in previous trials have engaged in questioning and argument to suggest that Sasinowski met with the FDA through an informal backchannel to present a position on the proposed label change that would not be made public.

AbbVie contends that evidence of Sasinowski's meeting is inadmissible because lobbying activities are protected under the First Amendment and the so-called *Noerr–Pennington* doctrine. *See Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014) (*Noerr–Pennington* provides immunity from liability "for engaging in conduct . . . aimed at influencing decisionmaking by the government"). AbbVie also argues that Nolte lacks any good-faith basis to ask questions that suggest improper activities took place during the meeting or that the meeting concerned the proposed label change, and it maintains that it should not have to waive attorney-client privilege simply to rebut Nolte's false insinuations.

The Court disagrees that the *Noerr–Pennington* doctrine is applicable. Nolte does not seek to hold AbbVie *liable* for its alleged petitioning activity; he intends to offer evidence of that activity to demonstrate AbbVie's motive or intent. *See In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 306 (E.D. Pa. 2016) ("It would be a stretch to say that *Noerr–Pennington* bars any use of any evidence of the defendants' petitioning of the government, and its agencies, or evidence of any communications with the FDA."). There is no general rule that

evidence of activity that is protected by the First Amendment—speech, for example—is inadmissible. Indeed, a good deal of evidence regarding AbbVie's dealings with the FDA has been admitted without objection, and AbbVie has introduced some such evidence itself.

The Court is nevertheless concerned that Nolte lacks a good-faith basis to ask questions about whether Sasinowsksi's meeting with the FDA pertained to the agency's proposal to change the TRT class label, or to make argument suggesting it did. After the Court expressed doubts about whether details of the meeting were actually covered under attorney-client privilege, AbbVie disclosed the portion of the email that contained a discussion of the meeting. From the email, which the Court has reviewed in its entirety (including *in camera* review of a still-withheld paragraph), it does not appear that the proposed change to the class label was the subject of discussion during Sasinowski's meeting with the FDA that was discussed in the email. The Court therefore precludes evidence and argument regarding the meeting or what it concerned.

AbbVie has failed to make the case, however, that all evidence regarding its dealings with the FDA regarding the proposed label change should be excluded. As indicated earlier, its *Noerr-Pennington* challenge lacks merit. And to the extent Nolte is able to elicit evidence that gives rise to a reasonable inference that AbbVie's efforts vis-à-vis the FDA led the agency not to propose a label change—which evidence would be relevant and not unfairly prejudicial—he will have an appropriate basis to make argument to this effect in closing. The appropriate time to address the contours of any such argument is prior to closing arguments, when the Court will be able to assess the evidence that has been introduced. In the meantime, the Court precludes Nolte from

using in opening statement or during questioning of witnesses pejorative or potentially pejorative characterizations such as "back channel," "lobbyist," "lobbying," and similar terms.

11. Evidence or argument that "off-label" medical treatment is improper

AbbVie asks the Court to bar Nolte from introducing evidence or argument to suggest that it is illegal or improper for physicians to prescribe medication for purposes other than those that have been approved by the FDA. But AbbVie identifies no reason to believe that Nolte intends to offer any evidence or make any argument of that sort, and it conceded at the final pretrial conference that nothing like this has happened in any previous bellwether trial. Indeed, throughout this litigation, plaintiffs have taken the position that it is off-label marketing, not off-label prescribing, that is improper. The Court sees no reason why an additional bar on evidence is necessary and therefore denies AbbVie's motion.

Conclusion

As discussed in the body of this opinion, the Court grants in part and denies in part both Nolte's [dkt. no. 26] and AbbVie's [dkt. no. 27] motions *in limine*.

Date: January 6, 2018

MATTHEW F. KENNELLY
United States District Judge